UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,195	03/11/2004	Takuya Tamatani	14539-004014	5292

26161 7590 12/18/2006
FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
OUSPENSKI, ILIA I	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,195	TAMATANI ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *2-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/383,551.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 – 14 are pending.

2. Applicant's election without traverse of Group IV (a method of evaluating the effectiveness of a composition in treating or preventing experimental allergic encephalomyelitis, wherein the composition is an antibody) in the reply filed on 09/29/2006 is acknowledged.

Claims 2 – 4 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 1 and 5 – 14 are under consideration in the instant application.

3. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged.

However, the applications PCT/JP98/00837 and USSN 09/383,551 and 10/301,056, upon which priority is claimed, fail to provide adequate support under 35 U.S.C. 112 for claims 1, 10, and 11 of this application. Specifically, insufficient support was identified for the recitation in claim 1 of a method of evaluating the effectiveness of a generically recited "composition" in treating or preventing experimental allergic encephalomyelitis.

It is acknowledged that the priority documents disclose experiments evaluating the effect of an anti-JTT-1 antibody on experimental allergic encephalomyelitis, including determination whether the antibody prevents or reduces paralysis (see Example 14: pages 78 – 80 in the Certified English translation of PCT/JP98/00837 [PCT published as WO 98/38216], or pages 101 – 103 in the US applications 09/383,551 and 10/301,056). However, this is not deemed as providing sufficient support under 35 USC 112 for the claimed method of evaluating the efficiency of a generically recited "composition."

Consequently, claims 1, 10, and 11 have been accorded the priority of the filing date of the instant application, i.e. 03/11/2004.

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

4. As discussed supra, this application adds and claims additional disclosure not presented in the priority applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. Applicant is required to amend the first paragraph of the specification to reflect the correct status of this application as a continuation-in-part of the prior application.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP §608.01(o). Correction of the following is required:

The recitation in claim 1 of a method of evaluating the effectiveness of a generically recited "composition" in treating or preventing experimental allergic encephalomyelitis lacks proper antecedent basis in the specification.

It is acknowledged that the specification discloses experiments evaluating the effect of an anti-JTT-1 antibody on experimental allergic encephalomyelitis in an animal model of the disease, including determination whether the antibody prevents or reduces paralysis (Example 14 at pages 101 – 103). However, this is not deemed as providing proper antecedent basis for the claimed method of evaluating the efficiency of a generically recited "composition."

Applicant is requested to identify the written support for the claimed limitations identified supra. Alternatively, Applicant is invited to amend the specification to provide antecedent basis for the claimed subject matter.

6. The specification at page 1, paragraph 1, should be amended to reflect the status of the priority applications USSN 10/301,056 (Abandoned) and 09/383,551 (US Patent No. 7,030,225).

7. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies of foreign priority documents have been filed in parent Application USSN 09/383,551, filed on 08/29/1999.

8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

9. Applicant's IDS, filed 03/11/2004, is acknowledged, and has been considered.

Applicant's statement accompanying the IDS asserts that the listed references were submitted and/or cited by the Office in the "prior application." However, upon review of the files of priority applications USSN 10/301,056 and 09/383,551, the listed references have not been located. Certain references cited on the IDS have been located in the file of a related application USSN 10/107,828; these references have been considered and initialed. The remaining references have been lined through. Applicant is invited to submit the missing references to complete the record.

10. Claim 5 is objected to because of the following informalities: discordant use of terminology in the recitation of "wherein the composition is an antibody." It appears that "wherein the composition comprises an antibody" was intended. Appropriate correction is required.

11. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1 and 5 – 14 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that the elected invention is limited to a method of evaluating the effectiveness of a composition in treating or preventing experimental allergic

encephalomyelitis, wherein the composition is an antibody; however, the rejection is set forth with regard to the full scope of the generic claims as presently recited.

A. Claims 1 and 5 – 14 are indefinite, because the preamble of claim 1 recites a method for evaluating the effectiveness of a composition, without specifying the objective of the evaluation, i.e. the identity of the process that is being evaluated. In the absence of an appropriate preamble, the metes and bounds of the claim are unclear.

Applicant is invited to amend the preamble to clarify that the claimed method is for evaluating effectiveness of a composition in treating or preventing experimental allergic encephalomyelitis in an animal.

B. Claims 1 and 5 – 10 are indefinite because the recitation of method steps in claim 1 omits essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claim 1 recites the step of administering to an animal a composition that inhibits JTT-1 activity, followed by the step of determining whether the composition is effective in preventing or treating EAE. However, it is unclear how the step of "determining" is carried out, without a recitation of a specific positive step of evaluating the outcome of administering the test composition, such as e.g. the one recited in claims 11 – 14.

C. Claims 1 and 5 – 14 are indefinite in the recitation of JTT-1 antigen "activity," because the metes and bounds of the recitation are unclear. First, one of ordinary skill in the art would not be reasonably apprised whether the recitation encompasses the activity of the JTT-1 polypeptide as an antigen (i.e. in inducing an antibody response to JTT-1), or to other activities of the JTT-1 polypeptide. Second, since the instant specification does not provide a specific limiting definition of JTT-1 activities, the

recitation renders the claim vague and indefinite. The specification discloses (Example 13) that JTT-1 antigen "functions in the regulation of lymphocyte activation" (page 101, lines 4 – 5), and that an antibody to JTT-1 induces proliferation of peripheral blood lymphocytes when applied together with an anti-CD3 antibody (pages 100 – 101). Thus it is unclear which, if any, of these "activities," or any other activities, are encompassed by the claim, and therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

D. Claims 8 and 9 are indefinite in the recitation of "the polypeptide," because the recitation lacks antecedent basis in the base claim 5, which recites an antibody that binds to "the JTT-1 antigen" rather than a polypeptide.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

13. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1 and 5 – 14 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

A. Applicant is not in possession of a method which utilizes a generically recited "JTT-1 antigen."

The instant specification does not provide sufficient structural or functional description of the molecule recited under laboratory designation "JTT-1 antigen." The specification discloses at pages 12 – 13, bridging paragraph, that "JTT-1 antigen" is a transmembrane protein composed of a signal sequence, an extracellular region having a glycosylation site, a transmembrane region, and an intracellular region. Further, at pages 14 – 15, it is disclosed that the polypeptide "relevant" to a mammalian JTT-1 antigen (pages 14 – 15 bridging paragraph) comprises the amino acid sequence of SEQ ID NO:2 in which one or more [without limitation] amino acids are substituted, deleted, or added (page 15 lines 21 – 24). This is not deemed as sufficient written description of the recited genus of polypeptides in the absence of defining the relevant identifying characteristics such as the structure or other physical and/or chemical characteristics of the claimed genus.

Thus the claims, when interpreted in light of the specification, recite a genus of polypeptides comprising the amino acid sequence of SEQ ID NO:2 in which one or more, without limitation, amino acids are substituted, deleted, or added, but do not require that the encoded polypeptides share any testable functional activity, a feature deemed essential to the instant invention. Applicant has disclosed the sequences of "JTT-1 antigens" from rat, human, and mouse, and thus has disclosed only three species of the recited genus. In the absence of sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, the claimed invention is not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Attwood (Science, 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

Therefore, based on the instant disclosure as-filed, and in view of the teachings of the art at the time the invention was made, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities encompassed by the instant claims. Thus the generic recitation of a "JTT-1 antigen," especially in the absence of a testable function, does not reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

B. Applicant is not in possession of a method that utilizes a composition which inhibits a generically recited "activity" of a JTT-1 antigen.

The recitation of "activity" renders that claims indefinite, as addressed in detail in section 12 supra. The specification does not provide a specific limiting definition of JTT-1 "activity," making it unclear what is encompassed by the recitation. For examination purposes, the term is interpreted in light of the specification, which discloses that JTT-1 antigen "functions in the regulation of lymphocyte activation" (page 101, lines 4 – 5).

This disclosure is not deemed as sufficient to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the applicant was in possession of the claimed method, because one of ordinary skill in the art was aware that lymphocyte activation is a complex multifaceted process, which may affect some or all of T cell proliferation, maturation, migration, survival, secretion of various combinations of cytokines, and/or other processes (reviewed e.g. by Riley et al., 2005, Blood, 105: 13 – 21; see entire document, in particular, e.g. page 14, first column). Applicant has not disclosed which of these "activities" the JTT-1 antigen possesses, and which of these activities the recited "composition" must inhibit in order to be evaluated by the claimed method. Therefore, the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the recited "activity," and therefore, the claimed method. Consequently, Applicant was not in possession of the instant claimed invention.

C. Applicant is not in possession of a method of evaluating the effectiveness of a generically recited "composition" that inhibits JTT-1 antigen activity.

It is noted that the elected invention is limited to a method of evaluating the effectiveness of a composition in treating or preventing experimental allergic

encephalomyelitis, wherein the composition is an antibody; however, the rejection is set forth with regard to the full scope of the generic claims as presently recited.

The instant specification discloses experiments evaluating the effect of an anti-JTT-1 antibody on experimental allergic encephalomyelitis in an animal model of the disease, including determination whether the antibody prevents or reduces paralysis (Example 14 at pages 101 – 103). However, this is not deemed as providing sufficient written description to convey to those skilled in the art that the inventors, at the time the application was filed, had possession of the claimed method of evaluating the efficiency of a generically recited "composition" that inhibits JTT-1 antigen activity.

Applicant is not in possession of the genus of compositions that inhibit JTT-1 antigen activity (i.e. antagonists of JTT-1), because it was well known in the art at the time the invention was made that molecules having highly diverse structural and biochemical properties can function as antagonists. Huang (Pharmacology and Therapeutics, 2000, 86: 201 – 215; see entire document) reviews e.g. on page 202 the daunting task faced by the skilled artisan in developing e.g. small molecule regulators of protein function, and notes that the process requires long periods of trial and error testing. The structure of such molecules cannot be readily envisioned by one of skill in the art based upon the written description provided in the specification as-filed.

Applicant has disclosed a single species of the genus compositions that inhibit JTT-1 antigen activity, an anti-JTT-1 antibody; based on this disclosure alone, the skilled artisan cannot envision all the contemplated "compositions" that inhibit JTT-1 antigen activity, without a representative description of the structural and functional properties, or disclosure of sufficiently detailed, relevant identifying characteristics, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics, of the members of the recited genus.

D. Applicant is not in possession of a method comprising the step of administering to an animal a generically recited "substance" that is effective to induce experimental allergic encephalomyelitis (EAE).

The instant specification discloses a method of inducing EAE by administering to rats a mixture Hartley guinea pig cerebrospinal homogenate mixed with Freund's complete adjuvant (page 102 first paragraph).

However, a skilled artisan at the time the invention was made was aware that other methods of inducing EAE produce patterns of disease which are different from the one induced by cerebrospinal homogenate. For example, Dal Canto et al. (Microsc. Res. and Technique, 1995, 32: 215 – 229; see entire document) review that animals may be sensitized to either whole spinal cord homogenate or to specific isolated polypeptides; alternatively, the disease may be induced by administering sensitized antigen specific $CD4^+$ cells into syngeneic animals (e.g. page 224, first column, second paragraph). Dal Canto et al. teach that the latter method of disease induction is preferred, because it gives a closely reproducible pattern of disease in terms of timing of clinical presentation, pathological features, remission, and relapses (*ibid*). Therefore, since Applicant has provided a description of only one method of inducing EAE, and the various methods of inducing the disease result in different clinical manifestations, Applicant is not possession of the claimed method which includes the generic recitation of administering a "substance" that is effective to induce EAE.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

15. Claims 1 and 5 – 10 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a method of evaluating the effectiveness of a composition in treating or preventing EAE, wherein the method comprises a step of determining whether the composition prevents or reduced paralysis, does not reasonably provide enablement for the claimed method which does not include a recitation of a step of evaluating the outcome of administering the test composition.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, in the absence of a recitation of an essential method step.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The instant specification discloses a method of evaluating the effect of an anti-JTT-1 antibody on EAE, including the step of determination whether the antibody prevents or reduces paralysis (Example 14 at pages 101 – 103), as measured by disappearance of tension of the tail and paralysis of hind legs or of the whole body (page 102). However, one of skill in the art at the time the invention was made was aware that EAE has multiple manifestations, in addition to paralysis, which include weight loss, loss of piloerection, incontinence, and death (as reviewed e.g. by Fleming et al., 2005, Journal of Neuroimmunology, 170: 71 – 84; see entire document, in particular, e.g. Table 1 at page 72). Various studies employ different approaches to evaluating, measuring, and analyzing these parameters (e.g. pages 72 – 75). Furthermore, such variables as mean or median score, proportion of animals with specific characteristics or events, and length of time to an event (onset, peak, or relapse) are variously evaluated, leading to different and sometimes contradictory conclusions regarding the efficiency of a treatment (e.g. pages 75 – 77 and 82 – 83). Therefore, without sufficient guidance regarding the specific characteristics to be tested, one of skill in the art is left with a plethora of possible parameters to evaluate. In view of the unpredictability of the art, as reviewed by Fleming et al. (cited supra), the experimentation required to practice the claimed invention is unnecessarily, and improperly, extensive and undue.

16. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1, 10, and 11 are rejected under **35 U.S.C. 102(a) and 102(e)** as being anticipated by Rottman et al. (US Pat. Pub. No. 2004/0001831; publication date 01/01/2004; priority date 06/26/2002; see entire document), as evidenced by Webster's New Dictionary (1998, Simon & Schuster) at page 982, by Wekerle (Acta Neurol. Napoli 13, 197-204, 1991), and by the instant specification at page 102; alone or further in view of Applicant's Remarks filed on 03/11/2004.

It is noted that claims 1, 10, and 11 have been accorded the priority of the filing date of the instant application, i.e. 03/11/2004 (see section 3 supra). It is further noted that the elected invention is limited to a method of evaluating the effectiveness of a composition in treating or preventing experimental allergic encephalomyelitis, wherein the composition is an antibody; however, the rejection is set forth with regard to the full scope of the generic claims as presently recited.

A. Rottman et al. teach a polypeptide named ICOS (see entire document, in particular, e.g. the Abstract). One of skill in the art is aware that ICOS is an art-recognized synonym of JTT-1.

Rottman et al. further teach and claim a method of identifying a candidate ICOS-B7RP-1 inhibitor, the method comprising administering to a model animal with EAE a test compound, and determining whether the test compound abrogates a central nervous system phenotype of EAE (e.g. claim 24). The central nervous system phenotype includes loss of tail tone and posterior paresis (e.g. paragraph 0264).

Webster's New Dictionary (1998, Simon & Schuster) at page 982 provides evidence that paresis is a partial or slight paralysis.

The instant specification at page 102, lines 23 – 32, provides evidence that scoring of paralysis in EAE-affected animals includes evaluation of tail tension (tone), and slight paralysis (i.e. paresis) of hind (i.e. posterior) legs.

Rottman et al. teach (e.g. at paragraph 0232) that EAE may be induced in rodents by the method described in Wekerle (Acta Neurol. Napoli 13, 197-204, 1991). The reference of Wekerle provides evidence that the method cited by Rottman et al. is practiced in rats (e.g. page 198, first paragraph).

Therefore, in view of the evidence provided by the Webster's New Dictionary, the reference of Wekerle, and the instant specification, Rottman et al. teach all the limitations of the instant claims, and thus anticipate the instant claimed invention.

B. In addition to the reasons set forth supra, the instant claims are deemed to be anticipated by the reference of Rottman et al. in view of Applicant's explicit admission in the Remarks filed on 03/11/2004. Specifically, Applicant states: "Claims 1 – 14 appear to be directed to the same patentable invention as claim 24 of U.S. Patent Application No. 10/186,381 (Rottman and Kroczek), filed June 26, 2002, as set forth in U.S. Patent Application Publication 2004/0001831" (page 1, last paragraph).

Therefore, the teachings of the reference anticipate the instant claimed invention.

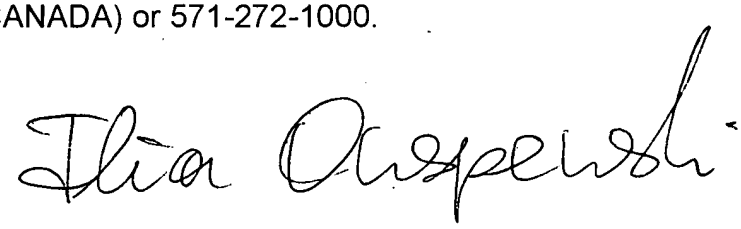
18. Conclusion: no claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.
Patent Examiner
Art Unit 1644



December 6, 2006